510(k) SUMMARY

EndoAid EndoRings

FEB 11 2014

Applicant Information:

EndoAid, Ltd.
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Israel

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Contact Person: Dan Rottenberg
Date Prepared: January 23, 2014

Device Information:

Trade Name:	EndoRings
Common or Usual Name:	Endoscopic Distal Attachment
Classification:	Class II per 21 CFR 876.1500
Product Code:	FED
Predicate Device:	Arc EndoCuff AEC 110; AEC 120; AEC 140 (K122565)

Device Description:

The EndoRings is a flexible silicone rubber add-on device designed to attach to the distal tip of the designated endoscope. The product features a short tube like shape with three flexible circular layers of wings that easily fold backwards during intubation and scope forward movement, and fold forward during scope withdrawal, to maintain the field of view and scope centering position.

Intended Use / Indications for Use:

The EndoRings is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following:

* Keeping the suitable depth of endoscope's view field

Technological Characteristics:

The technological characteristics of EndoAid EndoRings are equivalent to the characteristics of the predicate device.

Materials

The EndoRings silicone rubber material has been chosen as conforming to USP class VI and tested for biocompatibility in accordance with ISO 10993.

Size

The EndoRings length is 24mm, while the predicate Arc EndoCuff (K122565) length is 23.8mm. The main body tube outer diameter is 15.7mm for the EndoRings, and 17.2mm for the EndoCuff. There is a difference in the thin flexible wings /projections maximal free/open diameter which is 50mm for the EndoRings, and 34.8mm for the Arc EndoCuff. The wings fold easily when touching the colon walls, and the diameter of the wings can reduce to 22mm for the EndoRings compared to 17.4mm for the EndoCuff projections.

Non-clinical Data

The EndoRings is used to maintain the endoscopes field of view during endoscopy therapy by manipulating colonic folds, maintaining a central position in the lumen and avoiding sudden slippage. The nominated predicate device maximizes the field of view in a similar way.

The bench testing demonstrates that the EndoRings design combines some of the benefits of both being a slim and stabilizing cylindrical device (like the Arc EndoCuff), being able to stabilize and view the mucosa effectively on a greater diameter, without interfering with the standard field of view, since the wings are designed in a way they do not interfere with the endoscopic image.

The design of the device main cylindrical tube made from flexible polymer (silicone rubber) is the means of attachment / retention to the distal end of an endoscope (like the Endocuff).

The EndoAid EndoRings and the Arc EndoCuff both contact the patient in the same way and for the same period of time. Both are made from flexible polymers materials and both are sterilized.

The performance data showed that the sterilization method selected (EndoAid EndoRings is Ethylene Oxide sterilized and Arc EndoCuff is irradiated K122565) has not introduced any additional risks and the patient contacting materials have been tested for biocompatibility with reports demonstrating no negatives in safety or effectiveness.

The bench testing and clinical study has demonstrated that the device does not introduce any additional risks when undertaking endoscopic therapy and meeting the intended use.

All of these tests demonstrated that the EndoRings meets its intended performance specifications.

Clinical Data:

The device performance was validated by testing of a final production unit in clinical conditions. The procedures were performed at Elisha Medical Center, Haifa, Israel on a diverse adult population in terms of gender, ethnicity and age. Sixty (60) patients were enrolled in conformance with the device labeling.

The purpose of this prospective clinical study was to establish the feasibility and usability of the **ENDORINGS™** when used during standard colonoscopy procedures.

The primary endpoint was reaching the cecum of the colon with the **ENDORINGS**.

Secondary endpoints were:

1. Incidence of complications.
2. Ability to complete therapeutic interventions as biopsies, polypectomies, APC etc.
3. Procedure time
4. Ease of scope insertion, advancement and withdrawal.
5. Ability to center the scope inside the gastrointestinal tract.
6. Subjective evaluation of the additional area screened by the physician.
7. Patient wellbeing

Referring to the criteria above, the study objectives were met:

- Reaching the cecum: In 100 % of the cases, the primary endpoint, reaching the cecum, was achieved.
- Complications : Regarding secondary safety endpoints, there were no reports of adverse events, colon tissue damage, or other complications during the procedure or in the 24 hours post procedure follow-up.
- Therapeutic interventions: The ability to insert tool through the working channel and maneuver the scope distal tip to take specimen were tested: all the applicable answers were scored as "Good" to"Excellent". All of the interventions were successfully completed without any reports of operational difficulties.

- Device performance: The entire procedure was conducted without any interruption. There was no report of device malfunction or reliability failure.

- Scoring Analysis: None of the users rated any figure of merit as "unacceptable" or "difficult". All answers varied between "excellent" to "acceptable", while the vast majority of users' responses related to the device were rated as "excellent".

- Patient wellbeing: No adverse events, complications or complaints of patient discomfort were observed during the procedures or reported in the 24 hours follow up

The above test results and analysis, demonstrated that the EndoRings meets the user needs in clinical environment, under defined conditions. The test pass criteria were met. Thus, the clinical study supports the substantial equivalence of the EndoRings to its predicate device.

Substantial Equivalence:

After a review of the bench and clinical testing, the company concluded that the EndoRings is as safe and effective as the predicate device for facilitating endoscopic therapy.

The EndoRings and the predicate device have the same indication for use and very similar technological characteristics, and principles of operation. The minor technological differences between the EndoRings and its predicate device raise no new types of safety or effectiveness questions. In vitro verification testing and clinical study demonstrates that the EndoRings performs as intended and meets all design specifications with respect to their mechanical, functional and handling characteristics, and that its materials are biocompatible.

Thus, the EndoAid EndoRings is substantially equivalent to the Arc EndoCuff.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

EndoAid, Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K133359
Trade/Device Name: EndoRings
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: January 23, 2014
Received: January 23, 2014

Dear Janice M. Hogan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133359

Device Name
EndoRings

Indications for Use *(Describe)*

The EndoRings is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following:

Keeping the suitable depth of endoscope's view field

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.02.11 11:22:04 -05'00'

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